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ROBERT W. BECKER & ASSOCIATES
707 HIGHWAY 66 EAST
SUITE B
TIJERAS, NM 87059

EXAMINER	
MARMOR II, CHARLES ALAN	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,393	HOCHMAN ET AL.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed October 3, 2005. The Examiner acknowledges the addition of New claims 17-19. Claims 1-19 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claims 1 and 14, upon further review of Applicant's disclosure, the original disclosure of the instant application fails to provide support in full, clear, concise and exact terms that the combination probe, transceiver, and power source is *self-applied by a human subject into the human vagina.* The paragraph spanning page 6, line 17 to page 7, line 7 provides the only disclosure of the use of the apparatus of the instant invention. Assuming that the stimulator unit 21 is consistent with the claimed combination probe, transceiver and power source, the disclosure only provides that a woman removes the stimulator unit 21 from a holder or case 28 and that "the stimulator unit 21 is then inserted into the vagina." There is no explicit disclosure

that the woman inserts the stimulator unit into her own vagina. It is entirely possible that the woman is a doctor inserting the stimulator unit into the vagina of a second woman. Furthermore, it is not even clear that the vagina referred to in this passage is a human vagina in view of the paragraph at lines 4-10 of page 2 that indicates that the system may be used in other mammalian vagina. Therefore, this limitation comprises impermissible new matter.

Regarding claim 16, upon further review of Applicant's disclosure, the original disclosure of the instant application fails to provide support in full, clear, concise and exact terms that the combination probe, transceiver, and power source is *non-expandable and non-compressible in cross-section.* The paragraph spanning lines 7-15 of page 5 provides the only disclosure of the construction of the unit 21 which is believed to be consistent with the claimed combination probe, transceiver and power source. This paragraph only recites that the unit is sealed and made of plastic. There is no explicit disclosure that the unit 21 is non-expandable and non-compressible in any fashion, nor does the original disclosure even suggest that the unit 21 is rigid. It is entirely possible that a sealed, plastic unit be at least one of expandable and compressible. Therefore, this limitation comprises impermissible new matter.

Regarding claims 17-19, the original disclosure of the instant application fails to provide support in full, clear, concise and exact terms that the combination probe, transceiver, and power source is *insertable into a vagina without the use of a tool.* The paragraph spanning page 6, line 17 to page 7, line 7 provides the only disclosure of the use of the apparatus of the instant invention. Assuming that the stimulator unit 21 is consistent with the claimed combination probe, transceiver and power source, the disclosure only provides that a woman removes the stimulator unit from a holder or case 28 and that "the stimulator unit 21 is then inserted into the

vagina." There is no explicit disclosure how the stimulator unit is inserted into the vagina, i.e. whether a tool is used or not. It is entirely possible in view of this passage that a tool is used to insert the unit 21 into the vagina. Therefore, this limitation comprises impermissible new matter.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-13, 16, 17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "non-implanted" recited in line 4 of claims 1 and 16 renders the claims indefinite. No special definition of the term is set forth in the specification of the instant application. Moreover, the disclosure does not state or clearly suggest that the limitation "non-implanted" as used in the present application is intended to be interpreted in light of the FDA definition of the term "implant." Therefore, one cannot be certain of the metes and bounds of this term, which is a negative limitation, and thus the scope of the aforementioned claims.

In the Tenth Edition of Merriam Webster's Collegiate Dictionary (1996), the verb "implant" is defined as "to insert in a living site." In view of this "dictionary" definition of the word "implant," the limitation "non-implanted," or essentially not inserted in a living site, used in the claims of the present invention would appear to contradict subsequent limitations of the claims that require the device to be inserted into and contained within the vagina in order to monitor vaginal conditions, and therefore render the claimed apparatus inoperable.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-7, 11-13, 16, 17 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehrotra et al. ('859). Mehrotra et al teach a vaginal probe for monitoring various conditions within the vagina of a mammal. It is well known that humans are mammals. The probe includes at least a single, separate unit (see Figure 1) in the form of a portable, non-implanted, and intravaginally containable combination probe (18), transceiver (see column 8, lines 38-39), and power source (see column 4, lines 30-34 and column 7, lines 18-20). The probe communicates with a separate unit in the form of a combination controller and transceiver (receiver station/computer, see at least column 8, lines 43-53 and column 9, lines 8-16) that sends control signals to the probe to alter the transducing sensors (e.g. turning selected sensors off and on) and receives output signals from the probe and communicates with external networks, devices or databases. The single, separate controller and transceiver unit may be handheld for forming a wireless signal feedback loop with the probe unit. The probe unit is adapted to transduce vaginal conditions using a plurality of sensors (see at least column 7, lines 9-13 and column 8, lines 28-33) mounted on the probe. The sensors may be used to sense body temperature, the pH of cervical fluids and conductivity (means for sampling vaginal fluid), and motion and heart rate (which are inherently representative of muscle contractions). Other types of sensors may be

used. In another embodiment the probe may be adapted for medication delivery (see column 6, lines 6-8). The probe (18) is a sealed unit that may be inserted "in-situ" into the vaginal vault or removed therefrom. The probe (18) may be made of plastics or metals such that it is not expandable or compressible. In operation, the probe unit is capable of being self-inserted by a human subject into the human vagina without the use of a tool.

8. Claims 1-7 and 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Guice et al. ('39O). Guice et al. teach a system and method for monitoring the health and status of livestock and other animals. The system includes at least a single, separate unit (50,51,280) in the form of a portable, intravaginally containable combination probe, transceiver and power source in a single, separate unit (70,72) in the form of a combination controller and transceiver. The use of the transitional term "comprising" in the claim language is inclusive or open-ended and does not exclude additional, unrecited elements (i.e., in addition to the claimed two "single, separate units"). See MPEP 2111.03. The single, separate unit (50,51,280) in the form of a portable, intravaginally containable combination probe, transceiver (see at least paragraph [0124]) and power source (288) is "non-implanted" in a substantially equivalent sense as the limitation is defined in the specification of the instant application (i.e., "intravaginally containable... in situ yet removable" as recited in paragraph [0010]), although the patentee has chosen to call his telesensor an "implant." The Guice implant embodiments of Figs. 18 and 19 (see paragraph [0179]) are in the form of spring-like curved members that can be compressed to a smaller diameter to be inserted into a vaginal cavity, then expand to a larger diameter after being inserted into the vaginal cavity, and are provided with tabs (299) or a wire member (301)

to aid in removal of the telesensor implant without the need for incisions or surgery. The probes of Guice et al. (Figures 17-19) are not disclosed as being expandable or compressible along the width of the outer surface of the housing. The combination probe, transceiver and power source of Guice et al. is provided with means for sensing vaginal conditions (292) and 2-way wireless communication means for transmitting information that is transduced and for receiving control and programming signals (see at least paragraph [0124]). The separate combination controller and transceiver is provided with wireless means for sending signals to the probe and for receiving signals therefrom (see at least paragraph [0209]). A wireless signal feedback loop is provided between the controller and the probe and which may be an interactive or closed signal feedback wireless loop. The probe is a sealed unit which is inserted "in-situ" into the vaginal vault or removed therefrom (see at least paragraph [0135]). The means for sensing vaginal conditions of the probe include sensor transducers (292) that may be provided with means for transducing in the form of a muscle activity sensor (see at least paragraph [0080]); means for sampling temperature changes (see at least paragraph [0106]) in the vaginal environment. The wireless combination controller and transceiver includes means for wirelessly altering operation settings of the probe and means for wirelessly altering the transducing sensor (see at least paragraph [0104]). A wireless means (72) is provided to transmit signals to and/or receive signals from external devices, networks, or databases. The controller may be inclusive of a hand-held unit (e.g., a PDA). The probes (Figs. 17-19) of Guice et al. are capable of being self-applied by a human subject into the human vagina such that vaginal conditions are transduced by the probe.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehrotra et al. ('859) in view of Eini et al. ('037). Mehrotra et al., as discussed hereinabove, teach a combination probe, transceiver and power source that uses any of a variety of sensors to monitor conditions within the vaginal cavity. Mehrotra et al. teach all of the limitations of the claims except that the probe includes stimulating means. Eini et al. teach an intravaginal probe for sensing electrical activity of muscles surrounding the intravaginal cavity via sensors (24) and for electrically stimulating the intravaginal cavity in response to the sensed activity. The stimulation means (14) includes means for automatic adjustment of the stimulation levels in response to changes in the vaginal environment where the adjusting means is either programmed into the stimulating means or remotely adjustable via a wireless signal. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide an intravaginal probe similar to that of Mehrotra et al. with electrical activity sensors and stimulating means similar to those of Eini et al. in order to sense muscle activity in the vaginal cavity that effects a sensed vaginal cavity pressure and to stimulate vaginal muscles in response to the sensed body conditions of the human subject so as to prevent and treat conditions such as urinary incontinence.

11. Claims 1-7 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blythe ('118) in view of Mehrotra et al.

Blythe teach a vaginal probe for monitoring various conditions within the vagina of a human or animal. The probe includes at least a single, separate unit (10) in the form of a portable, non-implanted, and intravaginally containable combination probe and power source (68). The probe communicates with a separate unit in the form of a computer (75) that sends control signals to the probe to alter the transducing sensors (e.g. turning selected sensors off and on) and receives output signals from the probe (see column 7, lines 16-19) via a connection at interface port (72) and communicates with external networks, devices or databases. In one embodiment, computer is eliminated to make the probe unit portable. In this embodiment, the probe is a single separate unit in the form of a combination probe (10), transponder (92), and power source (68). The wireless combination probe (10) may be provided without the interface port (see column 8, lines 31-34). The probe unit is adapted to transduce vaginal conditions using a plurality of sensor transducers (42,44,46,48,50,52,56,58) mounted on the probe. The sensors may be used to sense body temperature, the pH of cervical fluids, Luteinising Hormone levels in vaginal fluids, cervical mucus density, estrogen levels, progesterone levels, estradiol levels, and vaginal cavity pressures which are inherently representative of muscle contractions (see column 2, lines 23-29 and 41-44). Other types of sensors may be used (see column 2, line 44). In another embodiment the probe may be adapted to apply treatment material for a condition (medication) such as semen or fertilized eggs to patients suffering from fertility issues (see column 9, lines 7-13). The probe is a sealed unit that may be inserted "in-situ" into the vaginal vault or removed therefrom. Nothing in the disclosure of the Blythe patent suggests that the

probe is either expandable or compressible. In operation, the probe unit may be self-inserted by a human subject into the human vagina (see column 7, lines 9-11). Blythe teaches all of the limitations of the claims except that the probe unit and controller unit include transceivers that provide a two-way wireless signal feedback loop between the combination probe unit and the combination controller unit.

Mehrotra et al., as discussed hereinabove, teach a combination probe, transceiver and power source that uses any of a variety of sensors to monitor conditions within the vaginal cavity of a mammal and forms a two-way wireless signal feedback loop with a combination controller and transceiver in order to control operation of the probe sensors and allow signals generated thereby to be received and analyzed at the external combination controller and transceiver unit to form a truly portable unit.

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention to provide an intravaginal probe that is self-inserted into the human vagina by a human subject similar to that of Blythe with transceivers similar to those of Mehrotra et al. in place of the computer interface and transponder of Blythe in order to make the probe fully portable by forming a two-way wireless signal feedback loop between the probe unit and the controller unit, enabling control of the sensors on the probe unit and transmission of signals generated by the sensors on the probe unit to the external controller unit for analysis.

Response to Arguments

12. Applicant's arguments filed October 3, 2005 with regard to the claim rejections under 35 USC § 112 have been fully considered but they are not persuasive. Applicant contends that

"non-implanted" is precisely an appropriate and proper term pursuant to FDA guidelines and requirements. Applicant further contends that the term "non-implanted" is the term of the art in the pertinent field, and is therefore definite, requires no definition since it is the term prescribed by the FDA, and is thus recognized by those in the industry to have specific metes and bounds. Applicant finally submits a number of FDA definitions to support his position that the meaning of the terminology to those of ordinary skill in the art in the relevant field. These arguments remain not persuasive.

The Examiner respectfully maintains the position that the FDA and the USPTO are different government agencies, and that metes and bounds of terminology required by one of those agencies is not necessarily applicable to the other. The Examiner points to the first sentence of the third paragraph of the FDA approval letter filed by Applicant on March 28, 2005 as Exhibit 3 in support of his position. The Examiner acknowledges the exhibits submitted by Applicant in support of Applicant's arguments, but respectfully notes that at no point does specification of the instant application direct one to definitions provided by the FDA for interpretation of the meaning of the term "non-implanted."

The definition of the term "implant" provided by the FDA and cited by Applicant in the remarks is directed to a noun. However, the term "non-implanted" as used by Applicant in the claims is an adjective that is used to modify a noun. Since Applicant's usage of the term is not consistent with the usage of the FDA, one cannot be certain that the definition of "non-implanted" as used by Applicant corresponds to and is consistent with the definition of the term "implant" provided by the FDA.

The Examiner maintains the position that absent any special definition of the term set forth in the specification of the instant application, one cannot be certain of the scope of this negative limitation. The Examiner respectfully submits that the specification of the instant application does not point one to the FDA for a definition of the term "non-implanted." As such, the Examiner contends that even one of ordinary skill in the medical arts would recognize that a device that is an "implant" as defined by the FDA may be considered "non-implanted" as required by the claim limitations of the instant application, before said device is surgically inserted into the body of a patient. Therefore, the Examiner maintains the position that one cannot be certain of the metes and bounds of this term and thus the scope of the aforementioned claims.

In view of the foregoing, the rejection of claims 1-13 and 16 under 35 U.S.C. 112, second paragraph, as being indefinite has been maintained.

13. Applicant's arguments filed October 3, 2005 with regard to the claim rejections under 35 USC § 102(b) and 35 USC 103(a) citing Blythe have been fully considered but are moot in view of the new grounds of rejection set forth in this office action.

Applicant first contends that Blythe does not teach or suggest that a 2-way wireless communication means for transmitting information that is transduced and for receiving control and programming signals. Applicant argues that transponders of Blythe form at best a one-way tracking signal that is sent from the probe to the external collar. While the Examiner does not concede that is argument is fully persuasive, the Examiner has set forth new grounds of rejection

hereinabove citing Mehrotra et al. which is believed to more clearly anticipate Applicant's invention, rendering this argument moot.

Applicant next argues that Blythe fails to teach or suggest a sealed probe unit. In support of this argument, Applicant contends that Blythe teaches that the end portion of the probe must be "maintained external to the patient" (column 7, lines 40 and 41) both to allow connection of the control cable 76 and to prevent fluids from entering the open or unsealed portion of the probe. The Examiner respectfully submits that while Blythe does teach that the end portion of the probe bearing interface port 72 is maintained external to the patient in order to allow connection of the control cable 76, Blythe does not teach or suggest that this is done to prevent fluids from entering this portion of the probe. The Examiner also notes that in the embodiment where the interface port 72 is eliminated (column 8, lines 31-34) the probe appears to be fully sealed. Applicant finally contends that the channel 40 of the Blythe probe provides further support for the unsealed nature of the Blythe device. The Examiner respectfully disagrees. At no time in the Blythe patent is there any disclosure or suggestion that fluids enter the probe housing of the Blythe probe. The channel 40 of the Blythe probe is formed on the exterior of the probe housing (see Figures 1-3) and the fluids collected in the channel 40 communicate with sensors (see 48) formed in the outer surface of the probe housing (see Figure 3). Nevertheless, these arguments are moot in view of the new grounds of rejection set forth hereinabove.

14. Applicant's arguments filed October 3, 2005 with regard to the claim rejections under 35 USC § 102(e) citing Guice have been fully considered but they are not persuasive. Applicant contends that the Guice reference is limited to use in animals and does not "anticipate" the

claims of the instant application because the device of Guice is an implant that is not adapted to be self-applied by a human subject into the human vagina. This argument is not persuasive.

With regard to Applicant's arguments that the "adapted to be self-applied" language is not merely an "intended use" but is a structural limitation that is a significant distinguishing feature between Applicants' system and the device of Guice, the Examiner respectfully disagrees. The limitation "adapted to be self-applied" is clearly directed to the intended use of the apparatus of the present invention. There is nothing relating to the structure of the apparatus that is limited by this limitation. More specifically, this limitation does not clearly require that Applicant's combination probe, transceiver and power source unit have any particular size, shape, or structural features that enable the device to be "self-applied." The Examiner submits that the disclosure of the instant application is entirely silent with respect to characteristics of the structure of the probe that adapt the probe to be self-applied by a human. In fact, further review of the original disclosure of the instant application reveals that the original disclosure does not provide explicit support for such a limitation as indicated in the new rejection under 35 USC § 112, first paragraph, set forth hereinabove. Since no structure of the probe is disclosed that particularly adapts the probe to be self-applied by a human, this limitation is at best directed to the intended use of the claimed combination probe, transceiver and power source. The Examiner maintains that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As discussed in detail in the Office Action of December 16, 2004, the Examiner contends that there is nothing in the structure of the Guice probes that

would prevent the probes from being inserted into the human vagina. That is, a human would be *capable* of self-inserting one of the Guice probes illustrated in Figures 17-19 into the vagina of said human whether or not the FDA approves or irregardless of whether it would be advisable to do so. Once disposed with a human vagina, a Guice probe would be *capable* of functioning properly to sense vaginal conditions, such as the temperature of vaginal walls or a general temperature within the interior of the vaginal cavity, particularly considering that the claims fail to require the probe to engage the interior of the vagina in any particular manner.

Regarding Applicant's argument that the use of a tool to insert a device precludes a device from being called "non-implanted," the Examiner respectfully disagrees. Many well known non-implanted gynecological devices that are adapted to by self-applied by a human into the human vagina utilize tools for applying the device. Among such devices are cytological samplers which use a tool to form a pathway into the vaginal canal and tampons which use a telescopic tool for application or insertion. It is believed that at least tampons are not considered implants, particularly in view of the definition provided by the FDA.

Regarding Applicant's argument that MPEP section 2111 requires that the USPTO apply the meaning of the term "non-implanted" as they would be understood by one of ordinary skill in the art, the Examiner respectfully submits that one of ordinary skill in the art would recognize that there is more than one possible way to interpret that term, as discussed in greater detail above. Absent any specific statement in the disclosure of the instant application, as originally filed, suggesting that Applicant is limiting themselves to the definition provided by the FDA each time the word "implant" or variations thereof are recited in the application, this term is open

to multiple and varying interpretations, particularly by one having ordinary skill in the pertinent art.

Regarding Applicant's argument that the FDA definition of implant (21 CFR 812.3(d), Exhibit 6) cannot be "loosely interpreted" to consider probes before they are inserted into a body as being "non-implanted" since this definition "means a device...intended to (comparable to "adapted to") remain there for a period of thirty days or more," this argument is not persuasive. The Examiner maintains the position that the disclosure of the instant application does not clearly direct one to the definition provided by the FDA when interpreting the limitation "non-implanted." Nevertheless, the FDA definition cited by Applicant and reproduced in this paragraph clearly includes the phrase "device... *intended to*" defining an intended use of the apparatus. For purposes of determining patentability of a device in the USPTO, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Irregardless, of whether or not Guice clearly intends his probe to remain in place for at least thirty days (or at least ninety days, as indicated in paragraph [0010]), there is nothing in the structure of the Guice that prevents one having ordinary skill in the art from removing Guice device from a subject prior to a period of 90 days, or even 30 days. After a detailed review of the disclosure of Guice, it appears that the Guice device would operate the exactly same whether it was removed after 90 days or after a substantially shorter period, such as after 7 days. Therefore, the limitation "non-implanted... probe" alone fails to provide sufficient structure in order to patentably distinguish the instant invention over that disclosed by the Guice reference.

In view of the foregoing and the arguments presented in the Examiner's previous Office Actions, the rejection of claims 1-7 and 11-13 under 35 U.S.C. 102(e) as being anticipated by Guice et al. ('390) has been maintained.

Regarding Applicant's comments suggesting additional limitations to claim 16 in an effort to define the instant application of the device of Guice by providing negative limitations that exclude the expandable and compressible characteristics of the Guice device, further review of the original disclosure of the instant application indicates that the original disclosure does not provide support for such limitations as indicated in the new rejection under 35 U.S.C. 112, first paragraph, set forth hereinabove.

15. The declarations under 37 CFR 1.132 filed October 3, 2005 are insufficient to overcome the rejection of claims 1-7 and 11-13 under 35 U.S.C. 102 (e) based upon Guice et al. as set forth in the last Office action. The Examiner acknowledges with respect and admiration the professional and educational accomplishments of Dr. Jayne and Dr. Wharton, and recognizes their respective degrees of expertise in their respective fields. However, the declarations submitted refer only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness/non-anticipation is commensurate in scope with the language of the pending claims. See MPEP Section 716. While both declarations show that it is not advisable by those skilled in the art to use the Guice device as claimed, both declarations fail to set forth facts that sufficiently prove that the Guice implant units are not *capable* of use in a human. Both declarations attempt to point to several teachings from the Guice reference as evidence that the

Guice implant units are not acceptable for human use and are not "non-implanted" devices. However, the teachings of Guice (e.g., the use of adhesives and tools to install the implant units) pointed to by Dr. Jayne and Dr. Wharton are not necessarily requirements of all embodiments of the Guice system as evident from the disclosure of paragraph [0042] of the Guice reference. The declaration of Dr. Jayne further repeatedly states that FDA standards and regulations and safety concerns support that the implant units of Guice may not be used in a human vagina; however, the declaration still fails to provide factual evidence to support that the Guice device is not *capable* of being used in the human vagina, irregardless of whether it is advisable to do so. The declarations ultimately only show that the Guice device would be unlikely to get FDA approval, is not advisable to be used in humans, and that one skilled in the art is unlikely to look to the Guice reference for a teaching or suggest with respect to how to use or configure a device to be used temporarily, in a non-implanted manner, in the human vagina. The lack of factual evidence provided in the declarations of Dr. Jayne and Dr. Wharton indicating that the structure of the instant invention, as defined by the language of the pending claims, patentably defines the structure of the present invention over that of the Guice reference is insufficient to overcome the rejection of claims 1-7 and 11-13 under 35 U.S.C. 102(e) as anticipated by Guice et al.

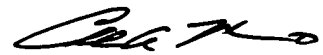
In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of non-anticipation and nonobviousness fails to outweigh the evidence of anticipation.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

cam
December 19, 2005